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09/631,000	08/02/2000	Michael L. Blomquist	9015.135US01	8019
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EXAMINER KOPPIKAR, VIVEK D				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/631,000

Applicant(s)

BLOMQUIST, MICHAEL L.

Examiner

VIVEK KOPPIKAR

Art Unit

3686

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2012.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-5, 7-19, 23, 24, 26 and 28-32 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-5, 7-19, 23-24, 26 and 28-32 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

Paper No(s)/Mail Date ____

DETAILED ACTION

Status of the Application

1. Claims 1-5, 7-19, 23-24, 26, and 28-32 been examined in this application. This communication is a Non-Final Rejection in response to the Request for Continued Examination (RCE) filed on February 7, 2012.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5, 7-19, 23-24, 26 and 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "first and second patient-specific parameters" is indefinite because it is not clear whether this phrase is (1) referring to the parameters of two different patients or (2) whether this phrase is referring to the two different parameters of the same patient. Appropriate correction and/or clarification is required.

For the purposes of examination, the Office will interpret this phrase to include both interpretations, which are set forth above.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 7-19 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,788,669 to Peterson in view of US Patent Number 5,713,856 to Eggers in view of in view of Official Notice and in even further view of JP7502678 (hereinafter referred to as JP'678) (this reference was listed in the IDS statement filed by the applicants on March 11, 2011).

(A) As per claim 1, Peterson discloses a method for creating a library of pump data on a computer having a database, the pump data being organized into sets of program data, each set of program data being available for batch downloading to a medical pump and including data items for controlling operation of the medical pump, the method comprising:

the plurality of data items forming a set of program data, (col. 4, lines 10-18 and lines 36-53).

Peterson teaches parameters (Col. 1, Ln. 20-21). In Peterson the memory is within the pump (Figure 1 and Col. 3, Ln. 50-65).

Peterson does not explicitly disclose at least some of the data items establishing parameters for controlling operation of a medical pump entering a plurality of data items into a database on the computer.

However, Eggers discloses at least some of the data items establishing parameters for controlling operation of a medical pump (i.e. drug libraries customized for each user ...) (col. 10, line 62 - col. 11, line 45) entering a plurality of data being patient-specific data items into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user ...)(col. 10, line 62 - col. 11, line 45).

Eggers also teaches the following: batch-downloading the plurality of data items into the memory within the pump and controlling operation of the pump based on one or more data items (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 7). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include at least some of the data items establishing parameters for controlling operation of a medical pump, entering a plurality of data items into a database on the computer as disclosed by Eggers within the Peterson system for the motivation of downloading complicated drug delivery profiles to the system (col. 2, lines 3-10 and col. 11, lines 14-20).

Peterson and Eggers do not explicitly disclose assigning at least one data key to the set of program data, the data key identifying the set of program data. However, the Office takes Official Notice that it was well known in the database arts to assign identifiers to data sets. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of Applicants invention to include assigning at least one data key to the set of program data, the data key identifying the set of program data within Peterson and Eggers for the motivation stated above.

The above references do not teach nor suggest the following feature which is taught by JP'678 (Abstract):

batch-downloading comprising downloading at least first and second patient-specific parameters without intervention from a user between the downloading of the first and second patient-specific parameters

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the above mentioned references with this aforementioned teaching from

JP'678 with the motivation of having a means of having a means of electronically (i.e. automatically, without intervention from the user) loading customized parameters into a drug infusion pump, as suggested/implied by JP'678 (Abstract).

(B) As to claim 2, Peterson does not explicitly disclose the method of claim 1 wherein the acts of: entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database.

However, Eggers discloses entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database (i.e. drug library (Col. 2, Ln. 3-10 and Col. 11, Ln. 14-26). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database as disclosed by Eggers within the Peterson system for the motivation of downloading complicated drug delivery profiles to the system (col. 2, lines 3-10 and col. 11, lines 14-2). Peterson and Eggers do not explicitly disclose assigning at least one data key to the set of program data includes entering the data key into a data key record and linking the data key record to the program data record.

However, the Examiner takes official notice that it was well known in the database arts to assign identifiers to data sets and linking data key records to application programs. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to include assigning at least one data key to the set of program data includes entering the data key

into a data key record and linking the data key record to the program data record within Peterson and Eggers for the motivation stated above.

(C) As to claim 3, Peterson does not explicitly disclose the method of claim 2 wherein further including entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump.

However, Eggers discloses further including entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump (col. 10, line 62 - col. 11, line 7). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump as disclosed by Eggers within the Peterson system for the motivation of downloading complicated drug delivery profiles to the system (col. 2, lines 3-10 and col. 11, lines 14-20).

(D) As per claims 7-19 and 23-24, these claims are substantially similar to claims 1-6 and are rejected on the same basis.

(E) As per claim 32, the combined teachings of Peterson in view of Eggers in view of Official Notice in view of JP'678 teaches that the plurality of data items includes at least one data item selected from the group consisting of data items related to delivery schedules, medication doses, and boluses (Eggers: Col. 10, Ln. 62-66). The motivation for making this modification to Peterson is the same as that set forth above, in the rejection of Claim 26.

6. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson in view Eggers in view of Official Notice in view of JP'678 as applied to claim 3 above, and further in view of "Acute Health Solutions'" DoseWatch to use Multum's MediSource (hereinafter Medisource).

As to claim 4, Peterson does not explicitly disclose the method of claim 3 wherein the computer is in data communication with a scanner, the method further comprising,

scanning a bar code with the scanner; and

entering the bar code into the computer, wherein the act of assigning at least one data key to the set of program data includes assigning the bar code to the set of program data.

However, MediSource discloses wherein the computer is in data communication with a scanner, the method further comprising:. scanning a bar code with the scanner; and entering the bar code into the computer, wherein the act of assigning at least one data key to the set of program data includes assigning the bar code to the set of program data (see abstract and page 2, paragraph 3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein the computer is in data communication with a scanner, the method further comprising: scanning a bar code with the scanner; and entering the bar code into the computer, wherein the act of assigning at least one data key to the set of program data

includes assigning the bar code to the set of program data as disclosed by MediSource with the combined system of Peterson, Eggers, Blomquist and Official Notice for the motivation to insure association of the drug and concentration with a pump rate and an infusion amount (Abstract).

As to claim 5, Peterson does not explicitly disclose the method of claim 3 wherein the computer is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump.

However, MediSource discloses wherein the computer is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump (Abstract and Page 2). It would have been obvious to one of ordinary skill in the art at the time of the invention to include a computer which is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump as disclosed by MediSource within the Peterson system for the motivation of insuring association of the drug and concentration with a pump rate and an infusion amount (Abstract).

7. Claims 26 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson in view of Eggers in view of US Patent Number 5,658,620 to Blomquist and in even further view of JP'678.

(A) As per claim 26, Peterson teaches a pump for infusing fluid into a patient (Peterson: Figure 1 and Col. 3, Ln. 50-65), the pump comprising:

a housing (Figure 1 and Col. 3, Ln. 50-65);

a pump mechanism positioned within the housing (Figure 1 and Col. 3, Ln. 50-65);

memory positioned within the housing and configured to store a plurality of data items being patient-specific data items forming a set of program data, at least some of the data items

establishing patient-specific parameters for controlling operation of a medical pump (Figure 1; Col. 1, Ln. 1-21 and Col. 3, Ln. 50-65)

and multiple program modules (Col. 3, Ln. 56-65 and Col. 4, Ln. 54-57).

Peterson does not explicitly disclose at least some of the data items establishing parameters for controlling operation of a medical PUDP entering a plurality of data items into a database on the computer.

However, Eggers discloses at least some of the data items establishing parameters for controlling operation of a medical pump (i.e. drug libraries customized for each user ...) (col. 10, line 62 - col. 11, line 45) entering a plurality of data items into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user ...)(col. 10, line 62 - col. 11, line 45).

The combined teachings of Peterson in view of Eggers do not teach or suggest individualized, patient-specific data parameters nor do they teach that at least one of individualized, patient-specific parameters are selected from the group consisting of an age, a weight, a delivery schedule, a delivery rate, dose requirements, limit for the size of bolus, limit for the frequency of boluses a dose, a bolus amount, a minimum time between boluses, a volume limit for delivery and a bolus frequency, however, this feature is taught in Blomquist (Col. 7, Ln. 63-Col. 8, Ln. 11 and Col. 11, Ln. 64-Col. 12, Ln. 10). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Peterson in view of Eggers with these aforementioned teachings from Blomquist with the motivation of having a means of allowing a user to download applications into a pump's flash

memory without having to enter the information through a keyboard, as recited in Blomquist (Col. 12, Ln. 4-11).

JP'678 teaches batch-downloading individualized, patient-specific parameters (JP'678: Abstract).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the above mentioned references with this aforementioned teaching from JP'678 with the motivation of having a means of having a means of electronically (i.e. automatically, without intervention from the user) loading customized parameters into a drug infusion pump, as suggested/implied by JP'678 (Abstract).

(B) As per claim 28, in Peterson the program data identifies a therapy name (Peterson: Col. 4, Ln. 47-53).

(C) As per claims 29-31, are these claims are substantially similar to claims 1-20, 23-24 and 26-28, above, and are rejected on the same basis as these claims.

Response to Arguments

8. Applicant's arguments with respect to the pending claims have been considered but, however, they are not persuasive.

The applicant appears to argue that the applied prior art references do not teach nor suggest "batch-downloading the plurality of data items into memory within the pump, the batch-down loading comprising downloading at least first and second patient-specific parameters without intervention from a user between the downloading of the first and second patient-specific parameters." However, as set forth above in the claim rejections, this feature is taught by JP'678 (Abstract). JP'678 (Abstract) teaches a loading tool for causing the system to

electronically (automatically) (i.e. without intervention from a user between the downloading of the first and second patient-specific parameters) load the customized library into the drug infusion pump. Earlier in the abstract of JP'678, the customized library is defined to include a plurality of drug entries. These plurality of drug entries (i.e. entries for two or more separate drugs) can be reasonably interpreted to constitute "first and second patient-specific parameters." Furthermore, it appears that in JP'678 this library, which contains these first and second patient-specific parameters, is loaded into an infusion pump all at once (i.e. without intervention from a user between the downloading of the first and second patient-specific parameters).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Jerry O'Connor, can be reached at (571) 272-6787. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair->

Art Unit: 3686

direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

/Vivek D Koppikar/

Primary Examiner, Art Unit 3686

5/16/2012